

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA; the States of
CALIFORNIA, COLORADO, CONNECTICUT,
DELAWARE, FLORIDA, GEORGIA, HAWAII,
ILLINOIS, INDIANA, IOWA, LOUISIANA,
MASSACHUSETTS, MICHIGAN, MINNESOTA,
MONTANA, NEVADA, NEW HAMPSHIRE,
NEW JERSEY, NEW MEXICO, NEW YORK,
NORTH CAROLINA, OKLAHOMA,
RHODE ISLAND, TENNESSEE, TEXAS,
VIRGINIA, WASHINGTON and WISCONSIN;
the DISTRICT OF COLUMBIA; THE CITY
OF CHICAGO and THE CITY OF NEW YORK,
ex rel., CHARLES ARNSTEIN and
HOSSAM SENOUSY,

Plaintiffs and Relators,

vs.

TEVA PHARMACEUTICALS USA, INC.,
TEVA NEUROSCIENCE, INC., and TEVA
SALES AND MARKETING, INC.,

Defendants.

No. 13 Civ. 3702 (CM)

**PLAINTIFFS-RELATORS' SUPPLEMENTAL BRIEF PURSUANT
TO THE COURT'S ORDER DATED DECEMBER 11, 2018**

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On behalf of the United States of America (“United States” or “Government”), Plaintiffs-Relators, Charles Arnstein and Hossam Senousy (collectively, “Plaintiffs” or “Relators”), respectfully submit this Supplemental Brief pursuant to the Court’s Order dated December 11, 2018.¹

I. INTRODUCTION

This is a civil action brought on behalf of the United States pursuant to the False Claims Act, 31 U.S.C. §§ 3729-33 (the “FCA” or “Act”), based upon Teva’s violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the “AKS”). Plaintiffs submit this Supplemental Brief and accompanying Supplemental Counterstatement of Facts pursuant to Fed.R.Civ.P. 56.1 (“SCS”), to specifically identify the evidence of record and other pertinent authority, which establishes the materiality of the AKS violations at issue under *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S.Ct. 1989 (2016)(“*Escobar*”). As discussed below, the evidence establishes that, under *Escobar*, there is no basis for summary judgment on the issue of materiality in this case.

II. PRELIMINARY STATEMENT

A. The Non-Exhaustive List Of Factors Enunciated In *Escobar* Regarding The Evaluation Of Materiality Under The FCA

Escobar held that “a misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government’s payment decision in order to be actionable under the False Claims Act.” *Id.* at 2002. In so holding, the Supreme Court observed

¹For the convenience of the Court and the parties, Plaintiffs adopt the same definitions and short-citations utilized in their Memorandum of Law in Opposition to Summary Judgment, unless otherwise specifically noted.

that “[u]nder any understanding of the concept, materiality ‘look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation,’” *Id.*, citing 26 R. Lord, Williston on Contracts § 69:12, p. 549 (4th ed. 2003), with the focus being on whether the misrepresentation at issue goes to “the very essence of the bargain.” *Id.*, quoting *Junius Constr. Co. v. Cohen*, 257 N.Y. 393, 400, 178 N.E. 672, 674 (1931). That is, “[m]ateriality ... cannot be found where noncompliance is minor or insubstantial.” *Id.* at 2003; *see also Bishop v. Wells Fargo & Co.*, 870 F.3d 104, 107 (2d Cir. 2017)(“*Bishop*”); *United States ex rel. Lutz v. Berkeley Heartlab, Inc.*, No. CV 9:14-230-RMG, 2017 WL 6015574, at *2 (D.S.C. Dec. 4, 2017)(“*Berkeley Heartlab II*”).

“[W]hen evaluating materiality under the False Claims Act, the Government’s decision to expressly identify a provision as a condition of payment is relevant, but not *automatically* dispositive.” *Id.* (emphasis added.)² “[P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement.” *Id.* And, “conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material.” *Id.* Likewise, “if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are

²Plaintiffs respectfully submit that *Escobar*’s use of the phrase, “but not automatically dispositive,” at least arguably suggests that it can sometimes be dispositive that a statute has been designated as a condition for payment and that this is why, as discussed below, the three other federal courts addressing materiality in the context of the AKS since *Escobar* have determined that compliance with the AKS is material as a matter of law.

not material.” *Id.* at 2003-04.

B. The Evidence Overwhelmingly Supports A Finding Of Materiality

The evidence establishes that Teva knew that compliance with the AKS went to the very essence of the bargain with the Government Healthcare Programs and that, by using its Speaker Programs to commit AKS violations, it could and would be held liable for such misconduct. *See also U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011)(citation omitted)(“[t]he Government does not get what it bargained for when a defendant is paid by CMS for services tainted by a kickback”). That is because, in its training and compliance materials, Teva repeatedly acknowledged the importance of the AKS with respect to Speaker Programs and the seriousness with which the Government treated AKS violations. *See SCS*, ¶¶ 2-4, 8.a.-8.8.c. Second, the evidence and case law establish that, at all pertinent times, compliance with the AKS was an important condition of payment for the Government Healthcare Programs. *SCS*, ¶ 7. Third, the evidence establishes that Teva repeatedly confirmed its knowledge of the importance of AKS compliance to Government payment decisions and that the Government was actively pursuing enforcement actions related to AKS violations with respect to Speaker Programs. *SCS*, ¶¶ 8.d.-8.w. Thus, the materiality of AKS violations is established in the record based on Teva’s own business records and admissions. Fourth, there is no evidence in the record that the Government ever had *actual knowledge* of any AKS violation giving rise to a claim for reimbursement and actually paid it. Fifth and finally, there is no evidence in the record to suggest that the Government regularly reimburses for claims that it knows result from AKS violations. As a result, Teva literally has no basis in the record evidence to assert a failure to establish materiality.

C. Materiality, Which Is A Mixed Question Of Fact And Law, Is Evaluated In A Holistic Fashion Under *Escobar*

The factors enunciated in *Escobar* are not exhaustive in nature. *Bishop v. Wells Fargo & Co.*, 870 F.3d 104, 107 (2d Cir. 2017)(“*Bishop*”)(quoting *Escobar* at 2003-04). Courts apply “a holistic approach to determining materiality in connection with a payment decision, with no one factor being necessarily dispositive.” *United States ex rel. Escobar v. Univ. Health Servs.*, 842 F.3d 103, 109 (1st Cir. 2016) (*Escobar II*). “[T]he fundamental inquiry is ‘whether a piece of information is sufficiently important to influence the behavior of the recipient.’” *Id.* at 110 (quoting *United States ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 211 (1st Cir. 2016)). In essence, “[t]he issue of materiality may be characterized as a mixed question of law and fact, involving as it does the application of a legal standard to a particular set of facts.” *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 450 (1976); *Lawrence v. Int’l Bus. Mach. Corp.*, No. 12CV8433 (DLC), 2017 WL 3278917, at *11 (S.D.N.Y. Aug. 1, 2017)(recognizing materiality as a mixed question of fact and law under the FCA).

Although “[s]uch questions ... are often reserved for the trier of fact..., they are ‘appropriately resolved as a matter of law’ where the misrepresentations or omissions ‘are so obviously important ... that reasonable minds cannot differ on the question.’” *Fed. Hous. Fin. Agency v. Nomura Holding Am. Inc.*, 68 F. Supp. 3d 439, 466 (S.D.N.Y. 2014), *aff’d sub nom.*, 873 F.3d 85 (2d Cir. 2017), *quoting TSC Indus.*, 426 U.S. at 450. Here, based upon the record in this case, and consistent with the other courts addressing materiality in the context of the AKS since *Escobar*, *see also United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 818 (S.D.N.Y. 2017), *motion to certify appeal granted*, No. 10-CV-5645 (JMF), 2017 WL 1843288 (S.D.N.Y. May 4, 2017), *and rev’d and remanded on other grounds*, 899 F.3d 163 (2d Cir.

2018)(“*Allergan*”)(“the Court has no trouble concluding that compliance with the AKS is a “material” condition of payment”); *Berkeley Heartlab II*, at *2 (“[n]o reasonable person could believe that AKS compliance is unimportant to the Government’s reimbursement decisions for laboratory services” and “[t]he “holistic” materiality analysis the Supreme Court set forth in *Escobar* demonstrates that AKS compliance is *per se* material”); *United States ex rel. Capshaw v. White*, No. 3:12-CV-4457-N, 2018 WL 6068806, at *4 (N.D. Tex. Nov. 20, 2018)(“The Supreme Court’s decision in *Escobar* presents this Court with a somewhat novel question: are AKS violations inherently ‘material’? ... The Court declines to expand *Escobar*’s protection to AKS violations”); *see also* United States’ Statement of Interest dated September 14, 2018 [Dkt. 138-1] at 7-9 (same), Plaintiffs respectfully submit that the Court could resolve this issue itself, holding that no reasonable person could conclude that compliance with the AKS was anything but material based on the facts of this case. In any event, at the very minimum, applying the holistic approach endorsed by *Escobar*, the record evidence establishes that genuine issues of material fact exist that preclude summary judgment.

III. ARGUMENT

A. Compliance With The AKS Has Been A Condition Of Payment At All Pertinent Times

It is established that compliance with the AKS has been a condition of payment for the Government Healthcare Programs at all pertinent times. *See U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 43 F. Supp. 3d 332, 362–64 (S.D.N.Y. 2014)(“*Novartis V*”)(joining “the vast majority of the courts that have considered this issue in holding that compliance with the AKS was a precondition to payment of claims submitted to federal health care programs prior to the 2010 AKS amendment”); *see also* 42 C.F.R. § 423.505(h)(1)(effective March 22, 2005 and

requiring that all Medicare Part D plan sponsors certify with CMS that they comply with all “[f]ederal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. §§ 3729 et seq.), and the anti-kickback statute (section 1128B(b) of the Act”); SCS at ¶ 7 (confirming that participation in the state Medicaid programs requires certification of compliance with the AKS.) Thus, the first factor identified in *Escobar* is established and weighs strongly in favor of a finding of materiality.

B. Teva’s AKS Violations At Issue Go To The “Essence Of The Bargain” And Are Neither Minor Nor Insubstantial In Nature

As this Court held in *Novartis V*, “the AKS is a ‘critical provision’ of the statutory scheme governing federal health care programs, and ... compliance with the AKS is ‘central to the reimbursement plan of Medicare.’” *Id.*, 43 F. Supp. 3d at 363 *quoting United States ex rel. Bidani v. Lewis*, 264 F.Supp.2d 612, 615-16 (N.D. Ill. 2003). “Otherwise, ‘[r]eimbursement a claimant for the supplies would put the government in the position of funding illegal kickbacks after the fact.’” *Id.*, *citing Bidani* at 615-16. And, “‘Congress cannot have intended that those brazen enough to violate the Anti-Kickback Statute (thereby risking criminal penalties), yet clever enough not to be caught (thereby avoiding exclusion from participation), would have their claims for Medicare payment paid with government funds.’” *Id.* at 363-64, *quoting United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F.Supp.2d 39, 51 (D.Mass. 2011). “[T]he same logic applies to claims submitted to Medicaid and TRICARE, which are also governed by the AKS.” *Id.* at 364. “In short, AKS violations are serious and would have affected the government’s decision to reimburse the pharmacies prior to 2010; the government would have ‘refuse[d] payment’ of the claims, had it known that they were tainted by the pharmacies’ involvement in a

kickback scheme -- AKS violations are not mere technicalities that the government would have forgiven in making reimbursement decisions.” *Id.* at 364, *quoting U.S. ex rel. Conner v. Salina Reg’l Health Ctr., Inc.*, 543 F.3d 1211, 1220 (10th Cir. 2008); *see also Allergan*, 246 F.Supp.3d at 818 (holding that “violation of the AKS is a far cry from an ‘insubstantial’ regulatory violation like, say, requiring ‘that [government] contractors buy American-made staplers’ rather than foreign staplers,” *see Escobar*, 136 S.Ct. at 2004, and noting that “Congress has made it a felony offense punishable by up to five years in prison, *see* 42 U.S.C. § 1320a–7b, and, as noted, the law now provides explicitly that ‘a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim,’” *id.* § 1320a–7b(g)); *Berkeley Heartlab II*, *supra* at *2 (same); *see also* OIG’s A Roadmap for New Physicians, Fraud & Abuse Laws, <https://oig.hhs.gov/compliance/physician-education/01laws.asp> (emphasizing the importance of the AKS and that “kickbacks in health care can lead to: overutilization, increased program costs, corruption of medical decisionmaking, patient steering and unfair competition”); *United States v. Americus Mortg. Corp.*, No. 4:12-CV-2676, 2017 WL 4083589, at *2–3 (S.D. Tex. Sept. 14, 2017)(importance of certifications at issue supported finding of materiality). As the Court explained in *Allergan*, 246 F. Supp.3d at 817 (citations omitted), “[k]ickbacks are designed to influence providers’ independent medical judgment in a way that is fundamentally at odds with the functioning of the system as a whole.... If providers could demand payment for claims resulting from kickback violations, then the [AKS] would be meaningless.”

Here, the evidence of record also establishes the central nature of AKS compliance (and the materiality of false certification of such compliance), since violations of the AKS can result in prescriptions being written by physicians without “the patient’s best interest in mind and the

overall cost of healthcare [being] driven up by the payment of referral fees.” SCS, ¶ 2.

Moreover, Teva repeatedly acknowledged the materiality of the AKS in its [REDACTED]
[REDACTED], by emphasizing the AKS’s role in preventing and detecting [REDACTED]
[REDACTED] while
emphasizing the [REDACTED]. *Id.*, ¶¶ 8.a., 8.b., 8.c (emphasis added.)

Furthermore, in training and compliance materials, Teva also acknowledged and emphasized the importance and seriousness of AKS violations. *Id.*, ¶¶ 8.d., 8.e., 8.f., 8.g., 8.h., 8.i.. As a result, the second *Escobar* factor also is established -- which is relevant (and arguably dispositive in the absence of contrary evidence), and weighs strongly in favor of a finding of materiality.


C. The Evidence Confirms That Teva Knew That The Government Would Refuse To Pay Claims If It Had Knowledge Of Similar AKS Violations And That The Government Took Consistent Enforcement Actions When It Discovered AKS Violations Related To Speaker Programs

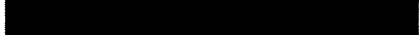
On May 5, 2003, the U.S. Department of Health and Human Services, Office of Inspector General (“OIG”), in its *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23731 (May 5, 2003) (“2003 *OIG Guidance*”), recognized that relationships with HCPs, such as arranging for Speaker Programs, could result in AKS concerns and that the 2002 PHRMA Code provided useful and practical advice for structuring relationships with HCPs to reduce the risk of fraud and abuse and demonstrate a good-faith effort to comply with the AKS. SCS, ¶ 8.i. Speaker Programs are an inherently risky practice in light of the AKS, SCS, ¶ 1, and Teva knew that its Speaker Programs could result in violations of the AKS because Teva knew and understood that, [REDACTED]

[REDACTED]. SCS, ¶¶ 1-4; *see also* *United States ex rel. Scutellaro v. Capitol Supply, Inc.*, Civ. No. 10-1094 (BAH), 2017 WL

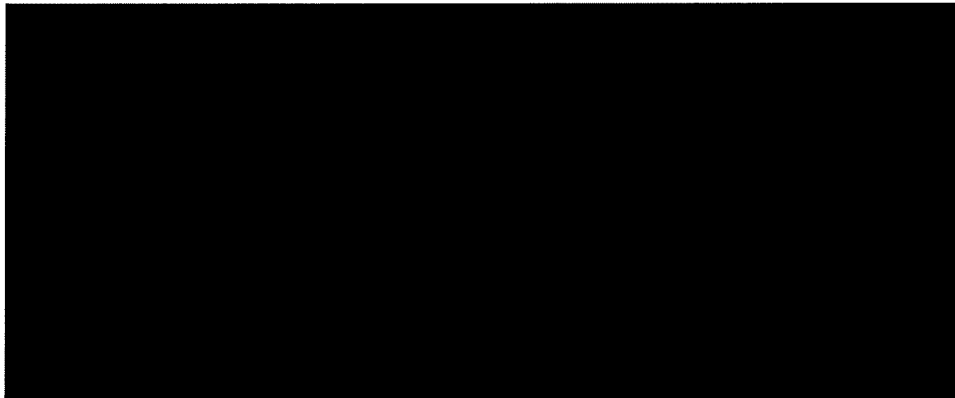
1422364, at *23 (D.D.C. Apr. 19, 2017)(GSA notices sent to defendant regarding non-compliant products raised genuine issue of material fact regarding materiality).

Teva itself characterized AKS violations as causing "[redacted]
[redacted]," SCS, ¶¶ 8.a., 8.b., 8.c (emphasis added), thereby confirming that it understood that the Government would refuse reimbursement for such claims if it became aware of AKS violations. In its training and corporate compliance materials related to Speaker Programs, Teva repeatedly emphasized that [redacted]



 Moreover, as Teva's own compliance expert acknowledged, OIG entered into more than 12 Corporate Integrity Agreements ("CIAs") with pharmaceutical manufacturers between 2006 and 2013 related to Speaker Programs and each referenced the AKS, as well as repayment obligations with respect to ineligible claims. SCS, ¶¶ 8.j.-8.u.; *see also* <https://www.justice.gov/usao-ndil/pr/pharmaceutical-company-pay-276-million-settle-claims-false-billings-federal-and-state> (in which Teva agreed to pay \$27.6 million to resolve claims related to "making payments to Dr. Michael J. Reinstein, a Chicago physician, in return for Reinstein prescribing an anti-psychotic medication to thousands of Medicare and Medicaid patients at dozens of area nursing homes and hospitals"); https://www.justice.gov/sites/default/files/usao-ndil/legacy/2015/06/11/pr0311_01a.pdf (Settlement Agreement at ¶ D (identifying payments to Dr. Reinstein as having been made in alleged violation of the AKS), ¶ 8 (referencing denials of claims for payment related to the conduct at issue)).

As early as August 28, 2008, and again on August 16, 2010, Teva received specific advice from its consultant about how seriously the Government treated AKS violations with respect to Speaker Programs:



[REDACTED]

SCS, ¶¶ 8.v-8.w (emphasis added.) This consulting report also states that, according to the OIG,

[REDACTED]

[REDACTED]” *Id.* Moreover, the report states that OIG

[REDACTED]

[REDACTED]” *Id.* Based upon its own admissions and acknowledgments of the ‘[REDACTED]’ associated with Speaker Programs, and the substantial enforcement activities by OIG and DOJ with respect to Speaker Programs violating the AKS, Teva clearly knew that the Government would refuse to reimburse for claims arising from AKS violations and, indeed, that it pursues civil and criminal enforcement actions when it discovers such violations. The extensive nature of the Government’s enforcement activities in this field with respect to the AKS generally and Speaker Programs specifically, as established by the evidence of record, alone establish the materiality of the AKS violations at issue. *See Grabcheski v. Am. Int’l Grp., Inc.*, 687 F. App’x 84, 87 (2d Cir. 2017)(in assessing materiality,

courts “look to ‘the effect on the likely or actual behavior of the recipient of the alleged misrepresentation’”); *United States ex rel. Rose v. Stephens Inst.*, 901 F.3d 1124, 1130-1134 (9th Cir.), *as modified by* 909 F.3d 1012 (9th Cir. 2018)(“Under the False Claims Act, ‘the term ‘material’ means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property,’ 31 U.S.C. § 3729(b)(4), and evidence that government department at issue “recouped many millions of dollars from the violating schools” supported conclusion that “a reasonable trier of fact could find that Defendant’s violations ... were material”); *United States v. Luce*, 873 F.3d 999, 1007–08 (7th Cir. 2017)(Government’s use of debarment proceedings in response to violations and defendant’s understanding of law and consequences supported materiality finding); *Miller v. Weston Educ., Inc.*, 840 F.3d 494, 504-505 (8th Cir. 2016) (defendant’s knowledge of government’s prior enforcement efforts against educational institutions for violations of Title IV’s recordkeeping requirements supported materiality finding); *United States ex rel. Grubea v. Rosicki, Rosicki & Assocs., P.C.*, 318 F. Supp. 3d 680, 701 (S.D.N.Y.), *reconsideration denied*, 319 F. Supp. 3d 747 (S.D.N.Y. 2018)(“*Rosicki*”)(materiality should be judged based on “how the Government reacted to similar misconduct when it had ‘actual knowledge’ of it”). That is because the “actual behavior of the recipient of the alleged misrepresentation,” confirms the materiality of AKS compliance to the Government. *Escobar* at 2002.

As the Court in *Berkeley Heartlab II*, *supra* at *2 (citations omitted), explained: “The Government routinely punishes AKS violations through criminal proceedings and civil proceedings to recoup funds,” and “[t]here can be no question that the Government would likely refuse to pay a claim that it actually knows is the result of an AKS violation.” *See also U.S. ex*

rel. Emanuele v. Medicor Assocs., 242 F. Supp. 3d 409, 431 (W.D. Pa. 2017), *reconsideration denied*, No. CV 10-245, 2017 WL 3675921 (W.D. Pa. Aug. 25, 2017)(evidence from “public records suggesting that health care providers have paid penalties after self-reporting similar violations” of the Stark Law “on at least nine occasions since 2009” weighed in favor of materiality finding and, “[o]n balance, a reasonable jury could find that the materiality requirement of the FCA is satisfied”). Thus, with respect to the third *Escobar* factor, the evidence similarly weighs strongly in favor of a finding of materiality.

D. There Is No Evidence Of Record That The Government Paid Any Claim In Full Despite Its Actual Knowledge That The AKS Was Violated Or That The Government Regularly Pays Claims Despite Knowledge Of AKS Violations

Teva has adduced no evidence that could support the fourth and fifth *Escobar* prongs -- that is, a finding that the Government paid any particular claim in full in this case despite its actual knowledge that the AKS was violated or, in the alternative, that the Government regularly pays claims arising from AKS violations in full despite actual knowledge that the AKS has been violated. *See Rosicki*, 318 F. Supp. 3d at 701 (“argument that the GSEs and the FHA knew of the fraudulent conduct at issue is pure speculation”).

Teva essentially argues that because certain Government Healthcare Programs *may* have continued to reimburse for Copaxone and Azilect after Plaintiffs’ initial Complaint was filed in this action and/or after the DOJ investigated certain of the allegations in Plaintiffs’ Complaint,³ those assertions somehow establish that the Government had “actual knowledge” of the AKS violations at issue. Not so.

³Plaintiffs note that Teva does not even point to any specific evidence of reimbursement by the Government Healthcare Programs or identify a date upon which it claims that the Government acquired “actual knowledge” of its AKS violations.

First, with respect to the allegations in Plaintiffs' Complaint, "mere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance." *United States ex rel. Streck v. Bristol-Myers Squibb Co.*, No. CV 13-7547, 2018 WL 6300578, at *15 (E.D. Pa. Nov. 29, 2018), *quoting Smith v. Carolina Med. Ctr.*, 274 F. Supp. 3d 300, 319 (E.D. Pa. 2017) (citing *Escobar II* at 110-12); *see also Bank of New York Mellon Tr. Co., Nat'l Ass'n v. Morgan Stanley Mortg. Capital, Inc.*, No. 11CIV505CMGWG, 2017 WL 733231, at *1 (S.D.N.Y. Feb. 10, 2017) (distinguishing between "constructive" and "actual" knowledge); *Flycell, Inc. v. Schlossberg LLC*, No. 11-CV-0915-CM, 2011 WL 5130159, at *8 (S.D.N.Y. Oct. 28, 2011) (distinguishing between "actual knowledge" and "constructive knowledge"); *see also Escobar II* at 112 (because there is no evidence of "actual knowledge of the violations," arguments regarding continued payment need not be considered). Here, there is no evidence in the record that the Government ever paid any claim with actual knowledge that it was tainted by a kickback. *See United States v. Berkeley HeartLab, Inc.*, No. CV 9:14-230-RMG, 2017 WL 4803911, at *7 (D.S.C. Oct. 23, 2017) ("*Berkeley Heartlab I*") (defendants failed to provide any evidence showing that the Government knew "that any claims were *actually tainted* by an illegal kickback scheme" and the Government "does not enjoy the luxury of refusing to reimburse health care claims the moment it suspects there may be wrongdoing"). The Court in *Berkeley Heartlab I* also noted that the defendants, as here, vigorously argued throughout the course of litigation that the elements of an FCA violation had been established, thereby undercutting the argument that the Government had actual knowledge all along. *Id.* Similarly, Teva cannot be heard to argue that the Government had *actual knowledge* that the AKS was violated and decided to still pay claims, while still contending that

it is entitled to summary judgment because Plaintiffs have failed to establish an AKS violation of any kind. Put another way, Teva's summary judgment motion is inconsistent with any finding of *actual knowledge* of AKS violations on the part of the Government and, at best, Teva's arguments conflate possible (albeit unproven) constructive knowledge with actual knowledge.

Second, with respect to the Government's investigation of Plaintiffs' allegations and the Government's subsequent decision not to intervene, Teva has not cited to a scintilla of evidence in the record as to what the Government investigated and/or what Teva produced to the Government as part of that investigation (or any basis to assert that the Government had "actual knowledge" of the AKS violations at issue at any time). The Government could have simply declined to intervene due to a lack of resources or because it lacked sufficient time to fully investigate the allegations. Teva certainly cannot prove that the Government was provided with evidence sufficient to acquire actual knowledge of the AKS violations at issue. Indeed, if anything, the decision not to intervene could be construed to suggest otherwise. Moreover, the evidence of record suggests that Teva has acted to actively conceal the nature of its AKS violations by misrepresenting the number of attendees at its Speaker Programs, monitoring its Speaker Programs on an infrequent basis (thereby avoiding a record being created of its actual conduct) and otherwise seeking to ensure that issues with Speaker Programs [REDACTED]. SCS, ¶¶ 5-6; *see also United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 906 (9th Cir. 2017)(if evidence suggested that FDA approval had been obtained through fraud, continued payment would not establish lack of materiality). Thus, although Teva can cite to no evidence regarding the information obtained by the Government as part of its investigation, the available evidence suggests that the Government could not have acquired

actual knowledge as part of its investigation, based upon Teva's misleading conduct.

Third, even if Teva could somehow establish that the DOJ acquired actual knowledge of the AKS violations (which it cannot), there is no evidence of record that the Centers for Medicare and Medicaid Services ("CMS") or any other government department paying claims had actual knowledge of any AKS violations. *See Escobar II* at 112 ("there is no evidence ... that MassHealth, the entity paying Medicaid claims, had actual knowledge of any of these allegations (much less their veracity) as it paid UHS's claims").

Fourth, Teva has not produced any evidence that CMS or any other government entity paying claims had actual knowledge that claims being submitted for reimbursement at any time were associated with Speakers who were being paid kickbacks, in violation of the AKS, or that Teva's misconduct regarding its Speaker Programs continued after Plaintiffs filed their initial Complaint. *See United States v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1050–51 (C.D. Cal. 2016)(defendant "cites Dr. Hay's expert report, which shows that CMS has continued to reimburse [for certain drugs] since this case was initiated in 2010," but "[t]his evidence is insufficient to show that CMS 'regularly pa[id]' claims for off-label uses of [these drugs] 'despite actual knowledge' that these uses were not medically accepted" because "[e]ven if CMS knew after 2010 that incoming claims for [such drugs] included claims that failed to meet the medical acceptance requirement, it does not follow that CMS had actual knowledge that particular claims were non-compliant and reimbursed them anyway"); *United States ex rel. Poehling v. UnitedHealth Grp., Inc.*, No. CV16086997MWFSSX, 2018 WL 1363487, at *12 (C.D.Cal. Feb. 12, 2018)(continued payments with knowledge of problematic conduct by Defendants "does not significantly change this analysis" because "generalized knowledge does

not amount to actual knowledge of specific” acts of misconduct giving rise to specific claims); *United States v. Coloplast Corp.*, 327 F.Supp.3d 300, 308 (D.Mass. 2018)(“jury could find that the government’s continued ... reimbursement claims has no bearing ... because it [could have] reasonably assumed defendant would not persist” in challenged activities). Teva has adduced no evidence, and no evidence exists in the record, that CMS would have any way of knowing which prescriptions were tainted by kickbacks at the time it made reimbursement decisions, or to determine whether a kickback was paid to a prescriber. *See Polansky v. Exec. Health Res., Inc.*, No. CV 12-4239, 2018 WL 1403433, at *7 (E.D. Pa. Mar. 19, 2018)(Medicare often “would have no way of knowing” whether any claim failed to comply with regulations).

Fifth and finally, there is no evidence in the record suggesting that the Government ever paid any claims (much less that it regularly pays claims) in full despite actual knowledge of AKS violations. Thus, as to *Escobar*’s fourth and fifth prongs, the evidence of record does not support Teva’s position and provides no basis for summary judgment.

E. Even If Teva Had Produced Evidence That The Government Paid Claims Arising From AKS Violations With Actual Knowledge, Material Issues Of Fact Would Remain Preventing Summary Judgment

Even if Teva could produce evidence that the Government paid claims arising from AKS violations with actual knowledge, such evidence would not be dispositive in this case. Although “the Supreme Court observed that ‘if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material,’ the Court did not state that such knowledge is dispositive.”

Escobar II at 110. As the Court in *United States v. DynCorp Int’l, LLC*, 253 F.Supp.3d 89, 102 (D.D.C. 2017), explained, “the fact that the government frequently pays charges when they are

billed and claws back unreasonable charges later does not demonstrate that reasonableness [of the charges] is immaterial” because “[t]hat would be like saying that because the IRS sometimes pays tax refunds before conducting audits, it does not care whether tax returns are accurate.” Moreover, under *Escobar*, materiality can be demonstrated even if the Government continued funding despite its knowledge of false certifications because “[t]hat must be a correct interpretation of *Escobar*; if it were not, then materiality would be impossible to demonstrate in cases ... where the Government continues to provide funding when it knows of false certifications because completely withholding the money would have an overwhelmingly deleterious and counterproductive effect.” *United States ex rel. Mei Ling v. City of Los Angeles*, No. CV 11-974 PSG (JCX), 2018 WL 3814498, at *19 (C.D. Cal. July 25, 2018); *United States v. Pub. Warehousing Co. K.S.C.*, No. 1:05-cv-2968-TWT, 2017 WL 1021745, at *6 (N.D. Ga. Mar. 16, 2017)(“The more essential the continued execution of a contract..., the less the government’s continued payment weighs in favor of the government knowledge defense”).

Although the Government has the authority to suspend payments to health care providers based on credible allegations of fraud, there are circumstances in which good cause may exist not to suspend such payments. 42 C.F.R. § 405.371(a), (b); *see also* SCS, ¶ 8.v., 8.w. (Teva knew that violations of the AKS could result in it being excluded from Government Healthcare Programs). The Government can elect not to suspend such payments if a beneficiary’s access to needed prescriptions would pose a danger to life or health, or because suspension would compromise an investigation or otherwise not be in the interests of the health care program. *See id.* § 42 C.F.R. § 405.371(b)(1). The drugs at issue are used to treat Multiple Sclerosis and Parkinson’s Disease. If the Government refused to reimburse for the Teva drugs at issue,

pharmacies might well refuse to dispense these drugs to patients, thereby jeopardizing certain patients' access to medical treatment. It also bears noting that, under the AKS, Plaintiffs "need only prove that 'one purpose' of remuneration is to induce a person to use a service for which payment is made under a federal health care program." *United States v. Teva Pharmaceuticals USA, Inc.* ("*Teva I*"), No. 13 Civ. 3702 (CM), 2016 WL 750720, at *17 (S.D.N.Y. Feb. 22, 2016). Therefore, if one accepted Teva's essential position (and assuming *arguendo* that Teva could establish the Government reimbursed tainted prescriptions with actual knowledge of AKS violations), that would require the Government to deny reimbursement for prescriptions for Copaxone and Azilect that might have been written for both legitimate and illegitimate reasons, while placing patient care and safety at risk. Plaintiffs respectfully submit that the unique nature of the AKS and the "one purpose" rule render analysis of the Government's continued payment of claims particularly inappropriate under the principles enunciated in *Escobar* -- in other words, continued payments do not have the same, if any, weight in an AKS case because the "one purpose" rule necessarily creates a different rubric through which the Government's conduct and knowledge should be evaluated. Moreover, since Plaintiffs contend that Teva caused pharmacies to submit false claims for the Subject Drugs that were written by physicians to whom Teva paid kickbacks, *Teva I* at *8, Teva's position would require the Government to deny reimbursement of claims to otherwise innocent pharmacies on the basis that the pharmacies should have somehow known or discovered Teva's AKS violations themselves. Under these circumstances, even if the Government continued payment for the claims at issue with actual knowledge of the AKS violations at issue (which it did not), there would have been good reasons to do so that were entirely unrelated to the question of materiality. Thus, even if Teva could establish

continued payments with actual knowledge, under the holistic approach to materiality required by *Escobar*, material issues of fact still would exist precluding summary judgment in this case because Teva's own documents consistently confirmed its knowledge of the importance the Government attaches to AKS compliance. *See Escobar*, 136 S.Ct. at 2002-03 (materiality depends on whether "a reasonable person would attach importance" to it or the "defendant knew or had reason to know" that the Government attached importance to it).

IV. CONCLUSION

For all of the reasons stated above, as well as the reasons stated in their Memorandum of Law in Opposition to Defendants' Motion for Summary Judgment dated September 13, 2018, Relators respectfully submit that Defendants' Motion for Summary Judgment should be denied.

Dated: December 21, 2018

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CERTIFICATE OF SERVICE

I hereby certify that on December 21, 2018, I caused the foregoing, as well as the accompanying Supplemental Counterstatement of Facts Pursuant to Local Civil Rule 56.1(b) to be electronically filed with the Clerk of Court using the CM/ECF system in redacted form, which will send notification to all counsel of record. I also certify that a copy of this Supplemental Brief and the accompanying Supplemental Counterstatement of Facts Pursuant to Local Civil Rule 56.1(b) in unredacted form was served by electronic and/or first class mail upon all counsel of record for Defendants.

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